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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,765	08/09/2001	Michael J. Mahan	220002060723	6765

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EXAMINER

FIELD, TAMMY K

ART UNIT - PAPER NUMBER

1645

DATE MAILED: 07/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/927,765

Applicant(s)

MAHAN ET AL.

Examiner

Tammy K. Field

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 31-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-26 and 31-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-25, drawn to immunogenic compositions that comprise a bacterium with a mutation in the DNA adenine methylase gene, classified in class 435, subclass 243.
 - II. Claims 26, 31-34 drawn to a method of generating an immune response, classified in class 424, subclass 234.1.
2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, wherein the products produced in Invention I can be used in the production of recombinant proteins, in diagnostic testing for antibodies, or as a control for comparison to wild type bacterium.

Election of Species

4. Invention I is generic to a plurality of disclosed patentably distinct species comprising various pathogens recited in Claims 6, 7, 12, 24, 25 and in specification, claim 11. Applicant is

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required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. The claimed species, each representing an independent and distinct set of bacterial immunogens that would elicit a different immune response:

- a. Haemophilus (claim 11, 13, 23)
- b. Escherichia (claims 6, 8, 24)
- c. Neisseria (claim 11, 12, 24, 25)
- d. Salmonella (claim 6, 7)
- e. Legionella (claim 24)
- f. Vibrio (claims 6, 9, 24)
- g. Yersinia (claims 6, 10, 24)
- h. Shigella (claim 11 and 24)
- i. Bordetella (claim 11)
- j. Pasteurella (claim 11, 12, 25)
- k. Treponema (claim 11)

5. Invention II is generic to a plurality of disclosed patentably distinct species comprising various pathogens recited in specification, claims 31, 32, 34. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. The claimed species, each representing an independent and distinct set of bacterial immunogens that would elicit a different immune response:

- a. Haemophilus (claim 32, 34)
- b. Escherichia (claim 31)
- c. Salmonella (claim 31)

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- d. Vibrio (claim 31)
- e. Yersinia (claim 31)

6. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. These inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification. Additionally, in the absence of restriction would place an undue burden on the examiner, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). If applicants elect Invention I, they should also elect species as set forth supra. Furthermore, if applicants elect Invention II, they should also elect species as set forth supra.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammy K. Field whose telephone number is (703) 305-4447.

The examiner can normally be reached on Monday-Friday from 7am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909.

Papers relating to this application may be submitted to Technology Center 1600 Group 1640 by facsimile transmission. The faxing of such papers must conform to the notice published

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in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-4426.

Patricia Duffy
PATRICIA A. DUFFY
PRIMARY EXAMINER